JUN - 5 2000

K 001597

510(k) SUMMARY

Submitted by: CONMED Corporation
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Date Prepared: May 22, 2000

Device Name: **CONMED TroGARD® Finesse™ Trocar System**
Common/Usual Name: Surgical Trocar
Classification Name: Laparoscope, General and Plastic Surgery
79 GCJ 21 CFR 876.1500

Predicate Device: **CONMED TroGARD® Dilating Trocar System** 510(k) K961175

Device Description:

The **CONMED TroGARD® Finesse™ Trocar System** is a conical, blunt-tipped dilating trocar consisting of a thermoplastic handle and obturator shaft that is used in conjunction with the **CONMED TroGARD® Trocar Sleeve** of 510(k) K954599. Working in concert with the trocar sleeve the conical tip is placed in a small incision made by the surgeon and by applying downward force the tip parts or splits muscle and fascial tissue. Once the tip of the trocar sleeve is within the body cavity the trocar can be removed to provide a pathway for surgical instruments. The device has applications in general surgical endoscopy and laparoscopy such as cholecystectomy and other such surgical procedures.

Intended Use:

The **CONMED TroGARD® Dilating Trocar System** (modified) devices are for use in establishing surgical access to the body cavity in surgical endoscopy including laparoscopy, pelviscopy, and thoracoscopy.

The **CONMED TroGARD™ Dilating Trocar System** has been in use and distribution for several years. In the laboratory setting the device was tested using animal tissue as the test media and access through the tissue simulating actual use conditions was obtained without difficulty. Clinical use of the device has been studied by independent clinicians and surgeons and their observations have been published in the literature. The literature expresses the advantages that have come to light through use and experience with conical, blunt-tipped trocars such as the **CONMED TroGARD® Finesse Trocar System** over that of the cutting type devices.

We conclude that the **CONMED TroGARD® Finesse Trocar System** is as safe and provides the same benefits as the devices currently marketed. And from the literature we conclude that the **CONMED TroGARD® Finesse™ Trocar System** provides for greater safety and clinical benefits than cutting type trocars.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K001697

Device Name: CONMED TroGARD® Finesse™ Trocar System

Indications for Use:

(Revised May 26, 2000)

For use in establishing surgical access to body cavity in surgical endoscopy including laparoscopy, pelviscopy, and thoracoscopy.

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Concurrence of CDRH, Office of device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001597

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-the-Counter _____